

REMARKS

Claims 87-107 are pending in this application. Claims 1-86 were cancelled, without prejudice.

Non-art Rejections

At paragraphs 2 through 16 of the Office Action spanning pages 2-9 various rejections under 35 U.S.C. § 112 have been raised. Applicants have extensively amended their claims in response to those rejections, and to conform to USPTO practice, in an effort to place all such amended claims in condition for allowance. No new matter has been added. Review of Applicants' amendments and withdrawal of the 35 U.S.C. § 112 rejections is respectfully requested.

Art rejections

At paragraphs 18 and 19, spanning pages 9-11 of the Office Action claims 87-95 and 100-104 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Patent Application Publication 2003/0013993 ("Jafari et al"). That rejection is respectfully traversed.

In the first instance the invention of Jafari et al. "Guidewire with Smoothly Tapered Segment" has little if anything to do with the subject matter of the present invention. The present invention as set forth, for example, in claim 87 relates to the structure on the terminal end of the guidewire not an intermediate "smoothly tapered segment" as disclosed by Jafari. This is readily seen even in the drawing i.e., FIG. 2, extracted into the Office Action at page 10. FIG. 2 is indicated at paragraph [0012] to be "a portion of the distal section of the elongated core member of the guidewire shown in FIG. 1." FIG. 2 does not show any structure where this invention would be applied. Moreover, the distal segment that is shown in FIG. 1/2 of Jafari et al. does not remotely disclose nor suggest the present invention.

Specifically, (and with reference to FIGS. 1 and 2 of this application) claim 87 requires "a terminal member extending axially from the guide wire, the terminal member tapering to a distal leading edge portion (designated in FIGS. 1 and 2 at "8") for engaging and gradually opening the occlusion...." As is described in the disclosure at page 16 the leading edge portion is "in the form of a chisel edge" and "extends at 90° to the main central axis". Further, at page 17 of the disclosure lines 13 et seq. it is noted that "convex surface 15 of the leading edge portion 8"...has a radius "r" that is "...sufficiently large to provide the leading edge portion 8 to be sufficiently blunt to prevent the leading edge portion 8 [from] penetrating a wall of a vessel of the vascular system, but not so blunt as would prevent the

leading edge portion 8 [from] penetrating an occlusion or partial occlusion in a vessel of the vascular system.” The present invention involves the details and structure of a device for recanalising a vascular occlusion. In short, it is the details of the extreme distal structure of the guidewire of this application that is inventive. Nothing of the sort is found in Jafari et al.

For example, Jafari et al. FIG. 1 shows the completed guidewire with a distal tip designated 18, 20, and 21. The structure shown at the distal end 18 of flexible segment [Jafari et al.’s invention] is a “body of solder 20” [paragraph 0025]. The “body of solder 20” clearly is a conventional atraumatic guidewire tip structure which is singularly unsuited to recanalising (i.e., forming a canal or channel—Stedman’s Medical Dictionary 26th ed.) a vascular occlusion as is the intended use for guidewires of this invention. FIGS. 3-8 of Jafari et al. depict partial guidewire structures, none of which disclose nor suggest the “terminal member” having the claimed structure of the present invention.

At paragraph 21 of the Office Action claims 96-99 stand rejected as being obvious under 35 U.S.C. § 103(a) over Jafari et al. in view of Patent Application Publication 2005/0065453 (“Shabaz et al.”). In paragraph 21 the assertion is made:

“In regard to claims 96-99, Jafari et al., disclose the feature of Applicants’ invention as described above.”

As discussed above that assertion is incorrect. Jafari et al. literally discloses only one completed guidewire structure and that completed structure thereof does not disclose nor suggest the critical “terminal member” as disclosed and claimed in the present application.

Shabaz et al. most certainly does not correct the deficiencies of Jafari et al. Shabaz et al. discloses a “biopsy device.” The biopsy system of Shabaz et al. includes a probe component 11. The probe component includes an elongated distal shaft 14 having a tubular section or cannula 15 with a tissue penetrating tip 16 [paragraph 0032]. It is not seen that there is the slightest disclosure suggesting that the “biopsy device” of Shabaz et al. has structure remotely useable in the distal segment of guidewire. In each and every depiction from Shabaz et al. of structure that could be applicable to a guidewire Shabaz et al. the structure designated “15,” is an extremely stiff, tissue penetrating cannula i.e., nothing that could be adapted for use in a guidewire.

Combining a rigid, piercing structure not in any sense even arguably useable or analogous to anything found in a medical guidewire to support an obviousness rejection would appear to be without technical foundation. It is submitted, therefore, that rejection of

claims 96-99 over the combination of Shabaz and Jafari et al., which lacks both technical and legal foundation, should be withdrawn.

At paragraph 22 of the Office Action claims 105 and 106 stand rejected as being obvious under 35 U.S.C. § 103(a) over Jafari et al. in view of Patent Application Publication 2002/0019644 ("Hastings et al."). In the analyses above Applicants have shown that Jafari et al. does not anticipate any of the independent claims of this application. Moreover, Applicants have shown that Jafari et al. in combination with Shabaz et al. does not support either legally or technically an obviousness rejection. Jafari et al. in view of Hastings et al. suffers the same deficiencies. Hastings et al. relates to a magnetically guided atherectomy device. The critical structure of this invention as set forth in claim 87 is discussed above. Claim 105 adds two additional requirements of the terminal member viz., that it be "radiopaque" and that it be "magnetic". The terminal member still must meet all the limitations of claim 87 viz., the "terminal member extending axially from the guidewire, the terminal member tapering to a distal leading edge portion..." as claims 105 and 106 both depend directly or indirectly from claim 87. Careful review of the device distal end structures shown in FIGS. 1-12 et seq.

The above also seems to ignore the fact that what Hastings et al. are disclosing is an atherectomy device not a guidewire. The clear distinction in this art between an atherectomy device and a guidewire is shown at paragraph [0005] of Hastings et al. wherein Hastings goes to great length to indicate that one of the drawbacks of a competitive approach to crossing a lesion i.e. balloon angioplasty, has the problem of "the vascular occlusion must first be crossed with a guidewire to position the balloon." The present invention is, in fact, an antecedent to utilization of balloon angioplasty to completely open i.e., "cross" a vascular obstruction. Clearly, if there was any hint or suggestion that the atherectomy device of Hastings et al. could be adapted to a guidewire structure such hint or suggestion would be found somewhere therein. As with the improperly proposed combination of a guidewire with a biopsy device which forms the basis for the obviousness rejection above based upon Jafari in combination with Shabaz et al, combining a guidewire reference with an atherectomy device reference also does not form the basis for an obviousness rejection.

Claim 107 stands rejected under 35 U.S.C. § 103(a) as being obvious over Jafari et al. in view of U.S. 5,135,483 ("Wagner"). Wagner is entitled "Atherectomy Device with a Removable Drive System." As with Hastings et al. analyzed above there does not seem to be the slightest technical or legal basis upon which to combine the guide wire with smoothly tapered segments of Jafari et al. with the atherectomy device of Wagner et al. Even

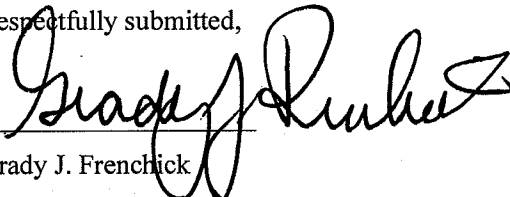
assuming some motivation to extract teachings from what Applicants contend is unrelated art reference, there does not appear to be an illustration or discussion of anything remotely approaching the subject matter of claim 107 given that claim 107 specifically incorporates "a terminal member of the guidewire of claim 87". Applicants remain willing to rewrite claim 107 but do not believe an obviousness rejection based upon Jafari et al. in view of Wagner et al. has either a logical, technical or legal basis.

Conclusion

For the reasons set forth above the rejections raised herein with respect to the claims, as amended, are not believed to be well founded and should be withdrawn. The undersigned is willing to discuss any aspect of prosecution of the above claims with the Examiner should such a discussion materially advance prosecution herein.

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Respectfully submitted,



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